

REMARKS

Claims 30-44 and 46-51 were pending when the outstanding Office Action was mailed on March 26, 2008. Claim 35 has been amended to clarify certain aspects of this claim. As such, claims 30-44 and 46-51 remain pending in this application.

In the Office Action dated March 26, 2008, all of the pending claims were rejected. More specifically, the claims were rejected on the following grounds:

(A) Claim 35 was rejected under 35 U.S.C. § 112, second paragraph; and

(B) Claims 30-44 and 46-51 were rejected under 35 U.S.C. § 103 over the combination of U.S. Patent No. 6,066,163 (John) and U.S. Patent No. 5,782,873 (Collins).

A. **Response to Section 112 Rejection**

Claim 35 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Although the applicants do not concede this rejection, claim 35 has been amended to delete "a physical therapy" and "a cognitive therapy." This removes the Examiner's substantive basis for the rejection.

The Examiner also indicated that claim 35 is an incorrect Markush claim. Claim 35 is not a Markush claim, but rather it defines the claimed process as including at least one of the listed acts. Unlike a Markush group, performance of the claimed process can include other acts as well. As a result, the applicants respectfully request withdrawal of the rejection of claim 35 under 35 U.S.C. § 112, second paragraph.

B. **Response to Section 103 Rejection**

Claims 30-44 and 46-51 were rejected under 35 U.S.C. § 103 over the combination of John and Collins. As explained below, however, this rejection should be

withdrawn because (a) a person skilled in the art would understand that John requires suprathreshold electrical stimulation and (b) the Examiner's rationale in combining John and Collins is fundamentally flawed.

1. John Requires Suprathreshold Electrical Stimulation

John is directed toward an adaptive feedback process that includes applying electrical stimulation to deep brain locations at an intensity intended to cause the neurons to fire so that an electrical response can be measured via electrodes at the cortex to determine a "measured present state." (John at 4:25-7:13.) John expressly discloses electrically stimulating deep brain locations, either with or without pharmaceutical stimulation or other external stimulation (e.g., auditory, visual or tactile stimulation), and then measuring the "present state" using EEG or evoked potentials via sensor electrodes implanted at the cortex. (John at 13:14-25 and 14:32-52.) The "measured present state" is then compared with a reference state to optimize the electrical stimulation. (John at 6:12-27.)

A person skilled in the art would understand that John requires the electrical stimulation to be suprathreshold stimulation. First, John expressly teaches that the electrical stimulation alone should cause a specific pattern of cellular firing that can be quantified to come up with the "measured present state." (John 13:14-25.) A person of ordinary skill in the art would understand this to mean that the electrical stimulation in John is suprathreshold stimulation. Second, one of John's primary applications is treating comatose patients, and as such the measured present state obtained via EEG or evoked potentials would require suprathreshold electrical stimulation for such patients. If the intensity of the electrical stimulation applied in John was subthreshold, the electrical stimulation by definition would not cause a consistent pattern of cellular firing that could be quantified to come up with the "measured present state." Thus, a person of ordinary skill in the art would understand that John requires suprathreshold electrical stimulation to perform his adaptive brain stimulation therapy.

2. Independent Claims 30 and 46 are Patentable Over the Combination of John and Collins because, *inter alia*, Modifying John to Use Subthreshold Electrical Stimulation as Proposed by the Examiner Would Render John's Method Inoperative

Claims 35 and 46 are patentable over the combination of John and Collins because a person of ordinary skill in the art would not modify John to use subthreshold cortical stimulation. A key aspect of John's method is measuring the present state of the patient's brain using electrodes implanted at the cortex in response to the applied electrical stimulation, and for the reasons explained above a person skilled in the art would understand that this requires suprathreshold electrical stimulation to consistently evoke the appropriate action potentials. Subthreshold stimulation, on the other hand, would not consistently evoke an electrical response that could be measured using a cortical electrode. Modifying John to use subthreshold electrical stimulation would accordingly render John's method for adaptive brain stimulation inoperative. Therefore, claim 35 is not obvious over John and Collins under Section 103.

The rejection of claim 35 over the combination of John and Collins is also incorrect because the Examiner's rationale supporting this rejection is fundamentally flawed. The Examiner's statements that "John discloses the device substantially as claimed" and that the only shortcoming of John is failing to teach "delivery of stimulation below a threshold level for neurons at the stimulation site" are fundamentally flawed for the following reasons:

1. The "device" shown in John provides deep brain stimulation for John's therapy, not cortical stimulation; the cortical electrodes in John are electrical sensors that sense the evoked electrical potentials caused by the deep brain stimulation.
2. John not only fails to teach delivery of stimulation below a threshold level for the neurons at the stimulation site, but a person skilled in the art would understand that John in fact requires suprathreshold

stimulation to carry out his methods for performing adaptive brain stimulation.

John accordingly does not disclose a device that is useful in the claimed cortical stimulation invention, and John teaches away from delivering stimulation below a threshold level. The Examiner's statement that John discloses the device substantially as claimed is incorrect such that one leg of the Examiner's rationale is flawed.

The other leg of the Examiner's rationale, namely the Examiner's assertion that a person of ordinary skill in the art would come up with the claimed method by modifying John to use a subthreshold stimulation signal as taught by Collins "to provide the predictable result of effectively lower [sic] the threshold of the sensory cells to facilitate the enhancement of therapy to the sensory cells," is also fundamentally flawed for several reasons. Collins teaches external stimulation of peripheral sensory cells so that a natural input signal can evoke an action potential at the sensory cells. If Collins' subthreshold stimulation was applied in John as taught by Collins, then external subthreshold stimulation would be applied to peripheral sensory neurons. In no way does Collins teach anything with respect to subthreshold electrical stimulation applied to the cortex. As a result, even if Collin's external subthreshold stimulation of peripheral sensory cells was combined with John's sensory stimulation inputs (e.g., auditory, visual or tactile) and/or electrical stimulation of deep brain structures, which the applicants do not concede, the resulting combination would still not teach applying subthreshold stimulation to the cortex. The Examiner's conclusion also completely disregards all of the teachings in John that require suprathreshold electrical stimulation to increase the chances that the firing pattern can be repeated and quantified to come up with the "measured present state." The Examiner's position accordingly incorrectly applies the teachings of John and is in fact in opposite to John's teachings. Thus, the rejection of claim 35 over Collins and John under Section 103 is incorrect and should be withdrawn.

Claims 31-44 and 47-51 depend from either independent claim 35 or 46. As such, claims 35-44 and 46-51 are patentable over John for the reasons explained above and also because the additional features set forth in these dependent claims.

In light of the forgoing, all of the pending claims comply with 35 U.S.C. § 112 and are patentable over the cited art. The applicants accordingly request reconsideration of the application and respectfully submit that the application is condition for allowance. If the Examiner has any questions or believes a teleconference would expedite prosecution of this application, she is encouraged to contact the undersigned representative at (206) 359-3258.

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Respectfully submitted,

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